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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,363	03/21/2002	Hiroko Matsunaga	NITT.0049	5840
38327	7590	07/15/2005		EXAMINER
REED SMITH LLP				KIM, YOUNG J
3110 FAIRVIEW PARK DRIVE, SUITE 1400			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22042			1637	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/009,363	MATSUNAGA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 27 April 2005.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-3,7-30 and 35-43 is/are pending in the application.  
 4a) Of the above claim(s) 13-30 and 35-43 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3 and 7-12 is/are rejected.  
 7) Claim(s) 1 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/27/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

The instant Office Action is responsive to the Amendment received on April 27, 2005.

### ***Preliminary Remark***

The Office acknowledges the cancellation of claims 4-6 and 31-34 in the Amendment received on April 27, 2005.

Claims 1-3 and 7-12 are under prosecution therefore.

With regard to the amendment made to claim 1, Applicants amended claim 1 to recite that the third filter is "hydrophobic." Claim 1 as originally prosecuted, however, recited that the third filter is "dydrophobic." As such term exists in prior art, Applicants are requested to provide specific section of the specification where support could be found with regard to the third filter being hydrophobic.

### ***Election/Restrictions***

This application contains claims 13-30 and 35-43 drawn to an invention nonelected with without traverse in the Election received on October 25, 2004.

Cancellation is suggested.

### ***Information Disclosure Statement***

The supplemental IDS correcting the typographical error of the reference cited in a previous IDS received on October 3, 2002 is acknowledged.

A signed copy of the PTO-1449 is attached hereto.

### ***Specification***

The Office acknowledges the new Abstract.

### ***Claim Objections – Necessitated by Amendment***

Claim 1 is objected to because of the following informalities: claim 1 recites the phrase, "said third filter is a hydrophic." It appears that the phrase should recite, "said third filter is hydrophobic."

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on February 10, 2005 is withdrawn in view of the Amendment received on April 27, 2005.

***Rejection – Necessitated by Amendment***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase, "said second filter captures polynucleotides eluted from the cells by denaturing agents poured from said upper opening *and holds or retains a PCR primer.*" The phrase is confusing because it is unclear whether the second filter already comprises the PCR primer therein (altering the structure of the second filter), or the second filter simply holds or retains the PCR primer when said primer is poured into the sample preparation unit (thus not

altering the structure of the second filter, as it is part of an intended use limitation). The latter assumption is made for the purpose of prosecution.

Claims 2, 3, and 7-12 are indefinite by way of their dependency on claim 1.

Claims 1 and 7 are indefinite for the following reasons.

Claim 1 recites that a second filter holds or retains a PCR primer and PCR amplification reaction mixture. However, claim 7 recites that the “space” between a first filter and a second filter holds or retains the PCR amplification reaction mixture. Therefore, claim 7 does not further limit claim 1, or claim 1 does not clearly define the invention so as to be further limited by its dependent claim 7. For the purpose of prosecution, it is assumed that the space between the first and second filters hold/retain the PCR amplification reaction mixture.

Claim 1 is indefinite for reciting the phrase, “heating block for raising and *lowering* the temperature of the solution retained in said second filter,” because while it is feasible for a heating block to raise the temperature (i.e., by *heating*), it is not clear how a heating block can actively “lower” the temperature of a solution.

Clarification is requested.

***Claim Rejections - 35 USC § 102***

The rejection of claims 6 and 9-12 under 35 U.S.C. 102(e) as being anticipated by Coplan (U.S. Patent No. 6,277,648, issued August 21, 2001, filed June 2, 1994), made in the Office Action mailed on February 10, 2005 is withdrawn in view of the Amendment received on April 27, 2005, canceling claim 6, and amending claims 9-12 to become dependent on claim 1.

The rejection of claims 6 and 31 under 35 U.S.C. 102(a) as being anticipated by Kuhara et al. (Japanese Patent Publication 10-257887, published September 29, 1998, IDS reference),

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made in the Office Action mailed on February 10, 2005 is withdrawn in view of the Amendment received on April 27, 2005, canceling the claims.

*Rejection – Maintained*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claim 1 under 35 U.S.C. 102(a) as being anticipated by Kuhara et al.

(Japanese Patent Publication 10-257887, published September 29, 1998, IDS reference), made in the Office Action mailed on February 10, 2005 is maintained for the reasons of record.

Applicants' arguments received on April 27, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments are addressed in the same order they were presented.

Applicants contend that Kuhara et al. do not teach the claimed sample preparation unit.

It should be made clear that the claim is drawn to an apparatus which, as one of the elements, comprises, a sample preparation unit.

Applicants state that in Kuhara et al., the gene fixation film is created in the reaction vessel and that the created gene fixation film is taken out and copies thereof are made, followed by the taking out of the produced gene fixation film and its insertion into the reaction vessel.

Applicants continue, that the claimed apparatus *must carry out polymerase chain reaction (PCR)*, and thus includes a heating block for raising and lower the temperature necessary for PCR amplification (page 20, bottom to page 21, 1<sup>st</sup> paragraph, Response).

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It appears that Applicants' arguments are drawn to the method of using the apparatus than the actual apparatus claimed.

Initially, the claimed apparatus does *not* necessarily carry out polymerase chain reaction. For example, a module of detecting nucleic acid hybridization could contain heating block so as to confer hybridization stringency but need not conduct PCR amplification. An apparatus is defined solely by its elements and their position with respect to each other. An intended use limitation (in which Applicants rely to distinguish their product) has no relevance to the product claim so long as the prior art product comprises all of the elements of the claimed product.

Reiterated, the "apparatus" of claim 1 is made up of its defined elements, said elements being:

a) at least one sample preparation unit, said sample preparation comprising:

i) an upper opening;

ii) a lower opening, and a channel connecting said upper and said lower openings

and provided with a first, a second and a third filter;

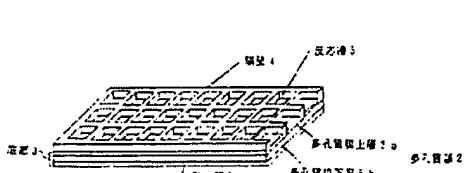
b) a holding unit for holding the sample preparation unit;

c) a heating block;

d) an irradiation means; and

e) a detection means, wherein the irradiation means is laser, the third filter is hydrophobic, and the detection means detects fluorescence.

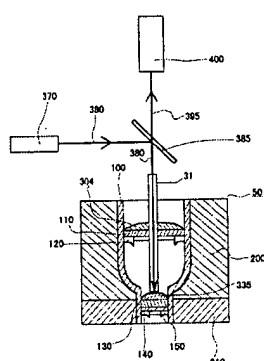
As already discussed in the previous Office Action, the gene analyzer of Kuhara et al. comprises an upper and a lower opening, connected by a channel comprising: a) waterproof membrane 1 as a lowermost layer; b) porous membrane



2 comprising at least two or more of a porous membrane upper layer 2a and a porous membrane lower layer 2b, differing in material, wherein said material is disclosed as functioning as a filter membrane (Solution section in the provided translation of the publication, see image reproduced).

Clearly, the gene analyzing of Kuhara et al. comprises three filters arranged in sequence as claimed in the instant claims.

With regard to the irradiation means and the detection means in claim 1, these means are a part of the apparatus, not part of the sample preparation unit. This is clearly evident in, for example, Figure 5 of the instant application:



The irradiation means (element 370) and the detection means (element 400), are clearly not a part of the sample prep unit (element 100). They are part of the apparatus.

Similarly, as Kuhara et al. demonstrates that the apparatus is as capable of analyzing many genes at a time by performing amplification, purification, immobilization of genes and hybridization in the same reaction sites. The artisans disclose that after the target genes are hybridized with markers, either radioactive or fluorescent, the results were detected, which would necessarily require that a detection means as well as the irradiation means be present, all of which would make up an apparatus [0021, Detailed Description].

Applicants contend that it would be "overreaching" to assume that the series of elements employed by apparatus would anticipate the apparatus as claimed since a laboratory typically contains many separate pieces of equipment for carrying out the experimental techniques

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discussed herein and that nowhere in Kuhara et al. is stated, or even suggested, that the same apparatus used for growing microorganism cultures, and filter components of those cultures, also includes an irradiation and detection means (page 21, 2<sup>nd</sup> paragraph, Response).

This argument is not found persuasive.

It appears that the term, "apparatus," employed by Applicants must be a dedicated apparatus for a single type of use. However, nowhere in the specification is the term, "apparatus," defined such a way. When the sample preparation unit of Kuhara et al. is placed in a detection system (which Kuhara et al. clearly evidences, by stating that their fluorescence is measured), that combination of the elements meets all of the limitation of the instantly claimed apparatus.

Therefore, the apparatus of Kuhara et al. anticipate instant claim 1.

***Claim Rejections - 35 USC § 103***

The rejection of claims 4-6 and 32-34 under 35 U.S.C. 103(a) as being unpatentable over Kuhara et al. (Japanese Patent Publication 10-257887, published September 29, 1998, IDS reference) made in the Office Action mailed on February 10, 2005 is withdrawn in view of the Amendment received on April 27, 2005, canceling the claims.

The rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Colpan (U.S. Patent No. 6,277,648, issued August 21, 2001, filed June 2, 1994) as evidenced by Shirasaki et al. (Japanese Patent Application publication No. 04-207195, published July 29, 1992, IDS

reference) made in the Office Action mailed on February 10, 2005 is withdrawn in view of the Amendment received on April 27, 2005, amending the claim to become dependent on claim 1.

***Rejection – Maintained***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 2, 3, and 7-12 under 35 U.S.C. 103(a) as being unpatentable over Kuhara et al. (Japanese Patent Publication 10-257887, published September 29, 1998, IDS reference) made in the Office Action mailed on February 10, 2005 is maintained for the reasons of record.

All of Applicants' arguments are directed to the propriety of the Kuhara et al. reference and as all arguments have been rebutted above, and no additional arguments have been made, the rejection is maintained for the reasons of record.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Inquiries***

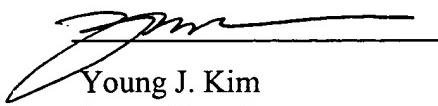
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to [Young.Kim@uspto.gov](mailto:Young.Kim@uspto.gov). However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official

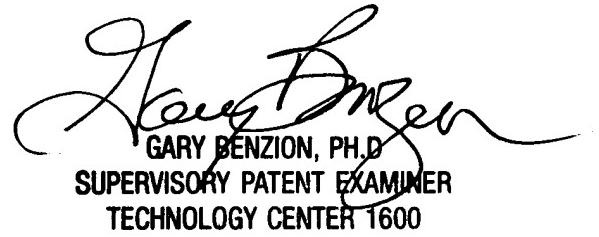
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documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Patent Examiner **YOUNG J. KIM**  
Art Unit 1637 **PATENT EXAMINER**  
7/9/2005

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